

REMARKS

This responds to the Final Office Action dated November 12, 2008.

Claims 1, 2, 3, 4, 7, 10, 11, 24, 26-28, 30, 32-35 and 38 are amended, claims 36 and 37 are canceled, and no claims are added; as a result, claims 1, 3-24, 26, 28-35 and 38 are now pending in this application.

Claim 37 is canceled. Applicant respectfully submits that any rejections of claim 37 are thereby moot.

Interview Summary

Applicant's representative greatly appreciates the courtesies extended by Examiners Stoklosa and Evanisko in the telephone interview of February 6, 2009. In the interview the claims, office action and cited references were discussed. Examiner Stoklosa tentatively agreed that the claims as presently presented appear to distinguish over the references of record and would accordingly reexamine the application.

Applicant's representative conducted a preliminary interview with Examiner Stoklosa on February 3, 2009 to request clarification regarding inconsistencies between the claim status on the Office Action summary page and the substantive rejections. Examiner Stoklosa indicated the claim status presented in the substantive rejections was the correct status.

§102 Rejection of the Claims

Claims 1-2, 4, 9, 11-12, 24, 26-28 and 34 were rejected under 35 U.S.C. § 102(b) for anticipation by Langberg (U.S. Patent No. 5,246,438). Applicant respectfully traverses the rejections of claims 1-2, 4, 9, 11-12, 24, 26-28 and 34 for at least the following reasons.

Claims 1, 2, 4, 9 and 34

Applicant respectfully submits the cited reference fails to show each of the claimed elements as described in claim 1. For example, Applicant cannot find in the cited reference:

at least one impedance monitoring conductive sleeve disposed within the insulating layer, the at least one impedance monitoring conductive sleeve continuously surrounds the conductor and extends continuously along the conductor from the proximal end to at least

the intermediate portion, wherein the at least one impedance monitoring conductive sleeve is physically isolated and electrically isolated from all sensing and therapy electrodes and all sensing and therapy conductors including the electrode and the conductor. See Claim 1.

Claims 2, 4, 9 and 34 depend from claim 1 and thereby include all of its recitations.

Applicant traverses the office action statement at page 2, paragraph 4, "Langberg discloses conductor 73 to be electrically isolated from all sensing and therapy electrodes through the use of a dielectric disk 78 (e.g. col. 9, line 55)." Applicant respectfully submits Langberg states at column 9, lines 51-57, "[a] distal end terminal 77 of helix 71 seamlessly joins with plated disk 82 . . . Metal disk 79 connects along its inside diameter to inner conductor 73. Dielectric disk 78 separates the metal disk 79 from the plated disk 82. *The three discs 82, 78 and 79 form a capacitor between inner conductor 73 and the helix 71.*" (Emphasis added). Langberg goes on to state at column 9, lines 50-51, "plated helix 71 seamlessly joins with the shield 69." Further, Langberg states at column 9, lines 47-49, "a proximal monitoring electrode 76, in the form of a ring, is seated on and makes electrical contact with the shield 69." Applicant respectfully submits that the conductor 73 is not physically and electrically isolated from all sensing and therapy conductors and electrodes as required by claim 1. Instead, as shown above, conductor 73 is in electrical communication with the helix conductor 71 through the capacitor circuit element disposed therebetween, and the helix conductor 71 is in electrical communication with the shield 69 and the proximal monitoring electrode 76.

In a similar manner, Applicant respectfully submits another embodiment, shown in Figures 3 and 4, of Lanberg fails to show each and every element of claim 1. Applicant previously traversed such an assertion from the Office Action dated August 20, 2008. For the convenience of the Examiner the remarks from the previous Office Action Response dated October 20, 2008 are resubmitted here.

Applicant respectfully traverses the Office Action statement at page 2, paragraph 3, "Langberg further discloses a shielding braid (Fig. 3, 45) that is metal and therefore conductive that is electrically isolated from the conductor by way of the dielectric material which is further covered by an insulating sleeve (Fig. 3, 57)." Applicant traverses this statement in so far as it appears to misinterpret Langberg. Langberg states at column 8, lines 1-4, "[a] distal monitoring electrode 56 is connected to a distal end terminal 48 of helix 50 and to bypass capacitor 55. Bypass capacitor 55 is connected to shield 45 through metallized coating 52 inside of core 51." Applicant respectfully

submits Langberg recites coupling of the shield 45 to the distal monitoring electrode 56. Langberg thereby fails to show at least electrical isolation of a conductive sleeve from all sensing and therapy electrodes and conductors, as recited in claims 1 and 24. Further, because the shield 45 is coupled to the distal monitoring electrode 56 and the electrode is exposed to the exterior environment of the ablation catheter, Langberg fails to show at least electrical isolation of a conductive sleeve from a lead body exterior environment as recited in claims 1 and 24. Because Langberg fails to show each and every element of the claims Applicant respectfully requests withdrawal of the anticipation rejections of claims 1-2, 4, 9, 24, 26-28 and 34.

In light of the remarks from the October 20, 2008 Response the present Office Action stated, “Applicant’s arguments, see Remarks, filed 10/20/2008, with respect to Claim 1 have been fully considered and are persuasive. The rejection of 8/20/2008 has been withdrawn.” Applicant respectfully submits the present rejection based on the configuration shown in Figure 5 of Langberg is traversed in a similar manner to the previous rejection based on the configuration shown in Figure 3 (see above). Applicant correspondingly requests withdrawal of the present anticipation rejections of claims 1, 2, 4, 9 and 34 for the reasons provided above.

Reconsideration and allowance of claims 1, 2, 4, 9 and 34 are respectfully requested.

Claims 11 and 12

Applicant respectfully submits the cited reference fails to show each of the claimed elements as described in claim 11. For example, Applicant cannot find in the cited reference, “a connector sized and shaped for connecting the means for detecting wear of the insulating layer with an impedance monitoring device.” Claim 12 depends from claim 11 and thereby includes all of its recitations.

Reconsideration and allowance of claims 11 and 12 are respectfully requested.

Claims 24, 26-28

Applicant respectfully submits the cited reference fails to show each of the claimed elements as described in claim 24. For example, Applicant cannot find in the cited reference:

at least one impedance monitoring conductive sleeve interposed between the lead body exterior and the conductor, the at least one impedance monitoring conductive sleeve at least partially surrounds the conductor, the at least one impedance monitoring conductive sleeve continuously extends along the conductor from the proximal end to at least the intermediate portion, wherein the at least one impedance monitoring conductive sleeve is

physically isolated and electrically isolated from all sensing and therapy electrodes and conductors including the electrode and the conductor. See Claim 24.

Claims 26-28 depend from claim 24 and thereby include all of its recitations.

As previously described above with regard to claim 1, Applicant traverses the office action statement at page 2, paragraph 4, “Langberg discloses conductor 73 to be electrically isolated from all sensing and therapy electrodes through the use of a dielectric disk 78 (e.g. col. 9, line 55).” Applicant respectfully submits Langberg states at column 9, lines 51-57, “[a] distal end terminal 77 of helix 71 seamlessly joins with plated disk 82 . . Metal disk 79 connects along its inside diameter to inner conductor 73. Dielectric disk 78 separates the metal disk 79 from the plated disk 82. *The three discs 82, 78 and 79 form a capacitor between inner conductor 73 and the helix 71.*” (Emphasis added). Langberg goes on to state at column 9, lines 50-51, “plated helix 71 seamlessly joins with the shield 69.” Further, Langberg states at column 9, lines 47-49, “a proximal monitoring electrode 76, in the form of a ring, is seated on and makes electrical contact with the shield 69.” Applicant respectfully submits that the conductor 73 is not physically and electrically isolated from all sensing and therapy conductors and electrodes as required by claim 1. Instead, as shown above, conductor 73 is in electrical communication with the helix conductor 71 through the capacitor circuit element disposed therebetween, and the helix conductor 71 is in electrical communication with the shield 69 and the proximal monitoring electrode 76.

In a similar manner, Applicant respectfully submits another embodiment, shown in Figures 3 and 4, of Lanberg fails to show each and every element of claim 1. Applicant previously traversed such an assertion from the Office Action dated August 20, 2008. For the convenience of the Examiner the remarks from the previous Office Action Response dated October 20, 2008 are resubmitted here.

Applicant respectfully traverses the Office Action statement at page 2, paragraph 3, “Langberg further discloses a shielding braid (Fig. 3, 45) that is metal and therefore conductive that is electrically isolated from the conductor by way of the dielectric material which is further covered by an insulating sleeve (Fig. 3, 57).” Applicant traverses this statement in so far as it appears to misinterpret Langberg. Langberg states at column 8, lines 1-4, “[a] distal monitoring electrode 56 is connected to a distal end terminal 48 of helix 50 and to bypass capacitor 55. Bypass capacitor 55 is connected to shield 45 through metallized coating 52 inside of core 51.” Applicant respectfully submits Langberg recites coupling of the shield 45 to the distal monitoring electrode 56.

Langberg thereby fails to show at least electrical isolation of a conductive sleeve from all sensing and therapy electrodes and conductors, as recited in claims 1 and 24. Further, because the shield 45 is coupled to the distal monitoring electrode 56 and the electrode is exposed to the exterior environment of the ablation catheter, Langberg fails to show at least electrical isolation of a conductive sleeve from a lead body exterior environment as recited in claims 1 and 24. Because Langberg fails to show each and every element of the claims Applicant respectfully requests withdrawal of the anticipation rejections of claims 1-2, 4, 9, 24, 26-28 and 34.

In light of the remarks from the October 20, 2008 Response the present Office Action stated, “Applicant’s arguments, see Remarks, filed 10/20/2008, with respect to Claim 1 have been fully considered and are persuasive. The rejection of 8/20/2008 has been withdrawn.” Applicant respectfully submits the present rejection based on the configuration shown in Figure 5 of Langberg is traversed in a similar manner to the previous rejection based on the configuration shown in Figure 3 (see above). Applicant correspondingly requests withdrawal of the present anticipation rejections of claims 24 and 26-28 for the reasons provided above.

Reconsideration and allowance of claims 24 and 26-28 are respectfully requested.

Claims 1-2, 4-9, 11-12, 24, 26-31 and 34 were rejected under 35 U.S.C. § 102(b) for anticipation by Webster (U.S. Patent No. 5,569,220). Applicant respectfully traverses the rejections of claims 1-2, 4-9, 11-12, 24, 26-31 and 34 for at least the following reasons.

Claims 1, 2, 4-9 and 34

Applicant respectfully submits the cited reference fails to show each of the claimed elements as described in claim 1. Further, the cited reference fails to show each element of claim 1 in as complete detail or as arranged in the claim pursuant to MPEP § 2131¹. For example, Applicant cannot find in the cited reference:

¹ See *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989), “The identical invention must be shown in as complete detail as is contained in the ... claim.” See also *Net MoneyIn, Inc. v. Verisign, Inc.* 545 F.3d 1359 (Fed. Cir. 2008), “Because the hallmark of anticipation is prior invention, the prior art reference—in order to anticipate under 35 U.S.C. § 102—must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements “arranged as in the claim.” *Connell v. Sears, Roebuck and Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983)”.

at least one impedance monitoring conductive sleeve disposed within the insulating layer, the at least one impedance monitoring conductive sleeve continuously surrounds the conductor and extends continuously along the conductor from the proximal end to at least the intermediate portion, wherein the at least one impedance monitoring conductive sleeve is physically isolated and electrically isolated from all sensing and therapy electrodes and all sensing and therapy conductors including the electrode and the conductor. See Claim 1.

Claims 2, 4, 9 and 34 depend from claim 1 and thereby include all of its recitations. Further, Applicant cannot find in the cited reference:

wherein the at least one impedance monitoring conductive sleeve has a first measured impedance value in a first condition, and the at least one impedance monitoring conductive sleeve is adapted for electrical isolation from a lead body exterior environment in the first condition, and the at least one impedance monitoring conductive sleeve has a second measured impedance value less than the first measured impedance value in a second condition where the insulating layer is breached and the at least one impedance monitoring conductive sleeve is in electrical communication with the lead body exterior environment. See Claim 1.

Applicant respectfully submits the Webster reference states at column 2, lines 49-59, “The tubular catheter body 12 comprises an inner wall 20, a first braided reinforcing mesh 24 . . . a second braided reinforcing mesh 34, and an outer wall or layer 40. Each of the first and second braided reinforcing meshes 24 and 34 comprise interwoven helical members.” Applicant submits that the meshes 24 and 34 of Webster necessarily include interstitial spaces between the interwoven helical spaces to preserve the flexibility of the catheter. The first and second braided reinforcing meshes 24 and 34 thereby fail to continuously surround the conductor and extend continuously along the conductor from the proximal end to at least the intermediate portion as recited in claim 1. Pursuant to MPEP § 2131, the cited reference fails to show each element of claim 1 in as complete detail or as arranged in the claim and Applicant correspondingly requests withdrawal the anticipation rejections of claims 1, 2, 4, 9 and 34.

Further, pursuant to MPEP § 2173.05(g), “[a] functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used.” Applicant respectfully submits that Webster fails to show the braided reinforcing meshes 24 and 34 function as an impedance monitoring conductive sleeve having a first measured value in a first condition, and a

second measured impedance value less than the first measured impedance value in a second condition where the insulating layer is breached and the at least one impedance monitoring conductive sleeve is in electrical communication with the lead body exterior environment. Instead, Webster states at column 1, lines 12-16, “The present invention relates to catheters, and more particularly to a cardiovascular catheter having an elongated catheter body reinforced with . . . layers of stainless steel braided meshes to provide high torsional stiffness.” Because Webster fails to show all of the recitations of claim 1 – including the functional recitations – Applicant respectfully requests withdrawal of the anticipation rejections of claims 1, 2, 4, 9 and 34 according to MPEP § 2173.05(g).

Reconsideration and allowance of claims 1, 2, 4, 9 and 35 are requested.

Claims 11 and 12

Applicant respectfully submits the cited reference fails to show each of the claimed elements as described in claim 11. For example, Applicant cannot find in the cited reference, “a connector sized and shaped for connecting the means for detecting wear of the insulating layer with an impedance monitoring device.” Claim 12 depends from claim 11 and thereby includes all of its recitations.

Reconsideration and allowance of claims 11 and 12 are respectfully requested.

Claims 24 and 26-31

Applicant respectfully submits the cited reference fails to show each of the claimed elements as described in claim 24. Further, the cited reference fails to show each element of claim 24 in as complete detail or as arranged in the claim pursuant to MPEP § 2131². For example, Applicant cannot find in the cited reference a connector sized and shaped for connecting the at least one impedance monitoring conductive sleeve with an impedance monitoring device, as recited in claim 24. Claims 26-31 depend from claim 24 and thereby include all of its recitations.

Further, Applicant cannot find in the cited reference:

² *Id.*

wherein the at least one impedance monitoring conductive sleeve has a first measured impedance value in a first condition, and the at least one impedance monitoring conductive sleeve is electrically isolated from a lead body exterior environment in the first condition, and the at least one impedance monitoring conductive sleeve has a second measured impedance value less than the first measured impedance value in a second condition where the insulating layer is breached and the at least one impedance monitoring conductive sleeve is in electrical communication with the lead body exterior environment. See Claim 24.

As previously discussed, MPEP § 2173.05(g) requires “[a] functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used.” Applicant respectfully submits that Webster fails to show the braided reinforcing meshes 24 and 34 function as impedance monitoring conductive sleeve having a first measured value in a first condition, and a second measured impedance value less than the first measured impedance value in a second condition where the insulating layer is breached and the at least one impedance monitoring conductive sleeve is in electrical communication with the lead body exterior environment. Instead, Webster states at column 1, lines 12-16, “The present invention relates to catheters, and more particularly to a cardiovascular catheter having an elongated catheter body reinforced with . . . layers of stainless steel braided meshes to provide high torsional stiffness.” Because Webster fails to show all of the recitations of claim 24 – including the functional recitations – Applicant respectfully requests withdrawal of the anticipation rejections of claims 24 and 26-31 according to MPEP § 2173.05(g).

Reconsideration and allowance of claims 24 and 26-31 are requested.

§103 Rejection of the Claims

Claims 3, 5-8, 10, 13, 29-33, 35 and 37-38 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Langberg (U.S. Patent No. 5,246,438) as applied above. Applicant respectfully traverses the rejections of claims 3, 5-8, 10, 13, 29-33, 35 and 37-38 for at least the following reasons.

Claims 3, 5-8, 10 and 35

Claims 3, 5-8, 10 and 35 are allowable at least as dependent claims of independent claim 1. Claim 1 is allowable because the cited reference fails to show all of the claimed elements, and Applicant respectfully submits claims 3, 5-8, 10 and 35 are allowable as dependent claims of claim 1.

Reconsideration and allowance of claims 3, 5-8, 10 and 35 are respectfully requested.

Claim 13

Claims 13 is allowable at least as a dependent claim of independent claim 11. Claim 11 is allowable because the cited reference fails to show all of the claimed elements, and Applicant respectfully submits claim 13 is allowable as a dependent claim of claim 11.

Reconsideration and allowance of claim 13 are respectfully requested.

Claims 29-33 and 38

Claims 29-33 and 38 are allowable at least as dependent claims of independent claim 24. Claim 24 is allowable because the cited reference fails to show all of the claimed elements, and Applicant respectfully submits claims 29-33 and 38 are allowable as dependent claims of claim 24.

Reconsideration and allowance of claims 29-33 and 38 are respectfully requested.

Claims 3, 10, 13, 32, 33, 35 and 37-38 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Webster (U.S. Patent No. 5,569,220) as applied above.

Claims 3, 10 and 35

Claims 3, 10 and 35 are allowable at least as dependent claims of independent claim 1. Claim 1 is allowable because the cited reference fails to show all of the claimed elements, and Applicant respectfully submits claims 3, 10 and 35 are allowable as dependent claims of claim 1.

Reconsideration and allowance of claims 3, 10 and 35 are respectfully requested.

Claim 13

Claims 13 is allowable at least as a dependent claim of independent claim 11. Claim 11 is allowable because the cited reference fails to show all of the claimed elements, and Applicant respectfully submits claim 13 is allowable as a dependent claim of claim 11.

Reconsideration and allowance of claim 13 are respectfully requested.

Claims 32, 33 and 38

Claims 32, 33 and 38 are allowable at least as dependent claims of independent claim 24. Claim 24 is allowable because the cited reference fails to show all of the claimed elements, and Applicant respectfully submits claims 32, 33 and 38 are allowable as dependent claims of claim 24.

Reconsideration and allowance of claims 32, 33 and 38 are respectfully requested.

Allowable Subject Matter

Claims 36 was objected to as being dependent upon a rejected base claim, but was indicated to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicant has amended claim 11 to include the subject matter of claim 36.

Reconsideration and allowance of claim 11 are respectfully requested.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's representative at (612) 371-2117 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on February 12, 2009.

Name Nicole Jack

Signature 